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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WASHINGTON, DC 20006

EXAMINER

PUTTLITZ, KARL J

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/785,013	Applicant(s) FUHRMANN ET AL.	
	Examiner Karl J. Puttlitz	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/362,730.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Various</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-19 are indefinite since these claims cover compositions, by virtue of the fact that these claims either require a solid (e.g., claim 15) or a pasty (e.g., claim 17), while claim 12, from which the rejected claims depend, covers a compound, and thus, those of ordinary skill would not know if the rejected claims cover compounds or compositions.

Claim 17, for example requires that the carnitine-magnesium hydroxycitrate is pasty. The term pasty is indefinite since those of ordinary skill would not be appraised of the term pasty, i.e., the exact water content of the claimed composition is not known.

Claim 18 depends on itself.

Prior Art Rejections

The claims cover, inter alia, carnitine-magnesium hydroxycitrate, wherein the magnesium, carnitine and the hydroxycitrate are present in a molar ratio 1:1:1.

The claims also cover those embodiments wherein the carnitine is L-carnitine.

The claims also cover those embodiments wherein the carnitine-magnesium hydroxycitrate is a solid.

The claims also cover those embodiments wherein the carnitine-magnesium hydroxycitrate is pasty.

The claims also cover a product by process for preparing the claimed carnitine-magnesium hydroxycitrate.

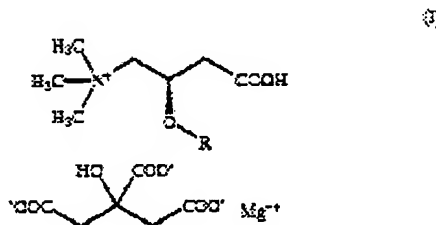
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/44918, as evidenced by U.S. patent No. 6,337,349 to Scafetta et al. (Scaffeta)

Scafetta teaches the following compounds at column column 2:



wherein R is a straight or branched lower alkanoyl having 2-5 carbon atoms.

The example discloses that preparation of a solid which was concentrated by a vacuum. Therefore, both solids and pasty preparations are disclosed.

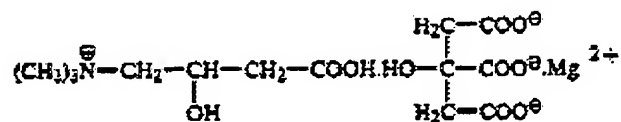
The difference between the compounds and compositions disclosed by Scafetta and those covered by the instant claims, is that while Scafetta teaches alkanoyl carnitine-magnesium hydroxycitrates, the claims cover the non-acylated carnitines. However, Scafetta teaches L-carnitines and its alkanoyl derivatives present the same therapeutic and nutritional activities (column 1, lines 18-23), and therefore, those of

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ordinary skill would be motivated to modify the disclosed alkanoyl derivatives and substitute with L-carnitine. Accordingly, Safetta teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Claim 12 is a product by process claim. In this connection, Scafetta substantially teaches the claimed carnitine-magnesium hydroxycitrate, and specifically, the record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Scafetta. See M.P.E.P. § ("[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . . . "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974).").

Scholl teaches the following compounds at column 1:



The difference between the compounds and compositions disclosed by Scholl and those covered by the instant claims, is that while Scholl teaches citrates, the claims cover hydroxycitrates. However, based on the disclosed citrates, the hydroxycitrate derivative is well within the motivation of those of ordinary skill. Therefore, Scholl teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Claim 12 is a product by process claim. In this connection, Scholl substantially teaches the claimed carnitine-magnesium hydroxycitrate, and specifically, the record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Scholl. See M.P.E.P. § ("[E]ven though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . . . "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974).").

Claims 12, 13, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0011081 by Claudio (Claudio).

Claudio teaches the coordinated use of L-carnitine or an alkanoyl L-carnitine or the pharmacologically acceptable salts thereof with hydroxycitric or pantothenic acid or derivatives thereof. By "co-ordinated use" of the aforesaid compounds it is meant indifferently either the co-administration, i.e. the substantially concomitant supplementation of L-carnitine or alkanoyl L-carnitine or a pharmacologically acceptable salt thereof and hydroxycitric or pantothenic acid or a derivative thereof, as active ingredients, or the administration of a combination preparation comprising a mixture of the aforesaid active ingredients, in addition to suitable excipients, if any. See paragraph 0002, first page.

The difference between the compounds and compositions disclosed by Claudio and those covered by the instant claims, is that Claudio fails to explicitly teach magnesium salts. However, Claudio does teach that any salt that does not give rise to undesirable side effects is suitable. In this regard magnesium salts are known to be physiologically and pharmacologically acceptable, and thus, well within the motivation of those of ordinary skill. Therefore, Claudio teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Claim 12 is a product by process claim. In this connection, Claudio substantially teaches the claimed carnitine-magnesium hydroxycitrate, and specifically, the record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Claudio. See M.P.E.P. § ("[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . . . "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims

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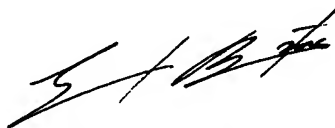
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at telephone number (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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